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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,048	01/11/2002	Stephen J. Brand	24492-006	8033

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Sonia K. Guterman, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C
One Financial Center
Boston, MA 02111

EXAMINER	
KAPUST, RACHEL B	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,048	BRAND, STEPHEN J.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *1-23,54-63 and 65-68* is/are withdrawn from consideration.

5)☒ Claim(s) *36,37,50 and 51* is/are allowed.

6)☒ Claim(s) *24-35,38,39,43-50 and 64* is/are rejected.

7)☒ Claim(s) *40-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0402,0103*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23 and 65-68, drawn to a pharmaceutical composition comprising a gastrin/CCK receptor ligand and an EGF receptor ligand, classified in class 530, subclass 350.

II. Claims 24-52 and 64, drawn to a method for treating a subject having diabetes, classified in class 514, subclass 2.

III. Claims 53-63, drawn to a method of reducing exogenous insulin usage in an insulin-dependent diabetic patient, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Group I and Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a composition comprising a gastrin/CCK receptor ligand and an EGF receptor ligand can be used in a variety of *in vitro* and *in vivo* assays and methods other than those recited in inventions 2-3, including the use of the compositions in *in vitro* cell free binding assays.

Group II is distinct from Group III because the methods are drawn to different conditions and thus have different goals and different outcome measures.

Because these inventions are distinct and/or unrelated for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the searches required for the different groups are different from each other, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Sonia Guterman on March 22, 2004 a provisional election was made without traverse to prosecute the invention of Group II, claims 24-52 and 64. Affirmation of this election, methods for treating a subject having diabetes, must be made by Applicants when replying to this Office Action. Claims 1-23, 53-63, and 65-68 are withdrawn from further consideration by the examiner as being drawn to a nonelected invention. Claims 24-53 and 64 are under consideration.

Priority

It is noted that this application appears to claim subject matter disclosed in issued patents 5,885,956 and 6,288,301. Although Applicants state that the current application is "related" to these patents, for benefit claims under 35 U.S.C. 120, the reference must include the relationship (*i.e.*, continuation, divisional, or continuation-in-part) of all nonprovisional applications. Priority is granted to provisional application 60/261,638, filed January 12, 2001, but priority is not granted to patents 5,885,956 and 6,288,301. The current application is not copending with patent 5,885,956 or 6,288,301, and Applicants have not perfected priority claims to patents 5,885,956 and 6,288,301 under 35 U.S.C. 120.

Specification

The use of the trademark INT™ (p. 3 and throughout the specification) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 38 is objected to because of the following informalities: there is a typo in claim 38 that reads "a gastrin/CCK receptor ligand and **an a** second effective dose..." (emphasis added). Appropriate correction is required.

Claims 29-31 are objected to because of the following informalities: claims 29-31 as written are drawn to a duration of treatment that is "less than about than about" a percent of an average human life span. This appears to be a typo in that the second "than about" should be deleted, and the claims should be drawn to a duration of treatment that is "less than about" a percent of an average human life span. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 43-49, and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 38 and 64 is drawn to methods of administering a composition over a term of "short duration". The term "short duration" is a relative term which renders the claims indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what time period would be considered to be a "short duration." One skilled in the art would not know what the metes and bounds of short duration are. Claims 43-49 are rejected as being dependent on claim 38.

Claims 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 is dependent on the method of claim 24, wherein "a duration of treatment" is less than about 0.3% of an average human life span. Claim 24 is also drawn to a duration of treatment. It is unclear whether the "duration of treatment" in claim 29 is a new duration of treatment or if it is meant to be a limitation on the duration of treatment of claim 24. If it is meant to be a limitation on the duration of treatment of claim 24, the rejection could be obviated by amending the claim so that it is drawn to "the duration of treatment". Claims 30-32 are rejected as being dependent on claim 29.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 is dependent on the method of claim 24, wherein "a period of remission" is at least about 0.5% of an average human life span. Claim 24 is also drawn to a period of remission. It is unclear whether the "period of remission" in claim 32 is a new period

of remission or if it is meant to be a limitation on the period of remission of claim 24. If it is meant to be a limitation on the period of remission in claim 24, the rejection could be obviated by amending the claim so that it is drawn to "the period of remission".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 24-28, 33-35, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,885,956 (Nardi *et al.*, submitted by Applicant in April 5, 2002 IDS). Claims 24-28, 33-35, and 64 are drawn to methods of treating subjects having diabetes by administering a composition having a first effective dose of a gastrin/CCK receptor ligand and a second effective dose of an EGF receptor ligand, the first and second effective doses being suitable for inducing islet neogenesis. The claims have limitations such as different biophysical effects, but in each instance the claims are drawn to administering a gastrin/CCK receptor ligand and a second effective dose of an EGF receptor ligand. In the specification, Applicant teaches that suitable dose ranges for intravenous and subcutaneous administration are generally about 0.1 micrograms or 1 microgram to about 1 milligram to 3 milligrams per kilogram body weight, or from about 20 to about 500 micrograms of each active compound per kilogram of body weight (p. 15). "Suitable dosage ranges for intranasal administration are generally about 0.01 pg per kg body weight, to about 1 mg per kg body weight. Effective doses may be extrapolated from dose-response curves derived from in vitro or animal model test systems. A daily dose is administered as a single dose or divided into a plurality of smaller fractional doses, to be administered several times during the day. Suppositories generally contain active ingredient in the range of about 0.5% to about 10% by weight; oral formulations preferably contain about 10% to about 95% active ingredient by weight."

Nardi *et al.* teach a method for treating diabetes mellitus by administering a composition comprising a gastrin/CCK receptor ligand and an EGF receptor ligand in an amount sufficient to effect differentiation of pancreatic islet precursor cells to mature insulin-secreting cells (see claim 1). According to Nardi *et al.*, suitable dosage ranges for intravenous administration are generally about 20-500 micrograms of active compound per kilogram body weight. Suitable dosage ranges for intranasal administration are generally about 0.01 pg/kg body weight to 1 mg/kg body weight. Effective doses may be extrapolated from dose-response curves derived from in vitro or animal model test systems. Suppositories generally contain active ingredient in the range of 0.5% to 10% by weight; oral formulations preferably contain 10% to 95% active ingredient" (column 6, lines 49-67). Thus, the same amount of the same composition is being administered for the treatment of diabetes. Any biophysical effects related to administering the composition of the current application would have also occurred in administering the same composition in the Nardi *et al.* patent. Thus, claims 24-28, 33-35, and 64 are anticipated by Nardi *et al.*

Claims 24-28, 33-35, and 64 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As stated above, claims 24-28, 33-35, and 64 are drawn to material either claimed or disclosed in the '956 patent. The inventors of the '956 patent are Nardi and Brand, whereas only Brand is the inventor of the current application.

Conclusion

Claims 36, 37, 51, and 52 are allowed.

Claims 40-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 24-35, 38-39, 43-50, and 64 are rejected.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

Wang *et al.* (1993), *J. Clin. Invest.* 92(3): 1349-1356

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK
6/21/04

JANET ANDRES
PATENT EXAMINER